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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/183,972	10/29/98	HAGEMAN G	UIA-027.01

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EXAMINER	
TURNER, S	
ART UNIT	**PAPER NUMBER**
1647	17

DATE MAILED: 10/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/183,972	Hageman
Examiner	**Group Art Unit**
Sharon L. Turner, Ph.D.	1647

☒ Responsive to communication(s) filed on *8-1-00*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-32* is/are pending in the applicat

Of the above, claim(s) *4-13 and 18-32* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3 and 14-17* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-32* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Sequence Requirements

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Full compliance with the sequence rules is required in response to this office action. In particular applicant is referred to the sequences of Figure 5 and page 41. Should these sequences be represented by a unique SEQ ID NO: already in computer readable format and the sequence listing, then applicant need only provide reference in the text to the appropriate SEQ ID NO. If no unique SEQ ID NO has been created for such sequences then one should be created.

Election/Restriction

2. Applicant's election with traverse of Group I, claims 1-3 and 14-17 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that since groups VI, IX and X are similarly classified that there is no burden on the examiner to search the prior art of the related subject matter. This is not found persuasive because the elements of the claims as set forth in the restriction requirement are not coextensive as the claims define different methods including identifying agents which bind to nucleic acids alternatively classified in class 435, subclass 7.1, a method of establishing a genetic profile alternatively classified in class 435, subclass 91.2 and

methods of selecting therapeutics alternatively classified in class 436, subclass 518. The methods use distinct reagents, steps and result in different outcomes.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 4-13 and 18-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO's:1, 3 and 5 which correspond to IPMC nucleotides. These SEQ ID NO's meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed and encompass hybridizing sequences, and sequences encompassing an IPMC gene which include sequences from upstream and downstream noncoding regions, sequences from other species, mutated sequences, allelic variants, splice variants, and sequences with homology which are not further described. None of

these sequences as recited by "hybridizing" and "IPMC gene" language meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO's:1, 3 and 5 of the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic acids and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific nucleic and amino acids are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO's:1, 3 and 5, but not the full breadth of claims meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-

Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

6. Claims 1-3 and 14-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The specification discloses nucleic acids which are purportedly useful in the detection of mutations in an IPMCgene resulting in a susceptibility to a disease, yet the specification fails to teach credible, specific and substantial utilities for this invention as the specification fails to define normal and abnormal IPMC genes and assays for such detection. Thus, the specification lacks a credible, specific and substantial asserted utility or a well established utility.

Claims 1-3 and 14-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above and elaborated below, one skilled in the art clearly would not know how to use the claimed invention.

7. Claims 1-3 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this

discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

A gene as defined by Lewin Ed., Genes IV, Oxford Univ. Press, 1990, pp. 810, is the segment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding region (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons). The specification teaches SEQ ID Nos 1, 3 and 5 but fails to teach normal IPMC genes, abnormal IPMC genes or sequences which can distinguish the aforementioned from each other.

Yet, the claims recite, polynucleotide sequences, hybridizing sequences and a kit for detecting mutations in an IPMC gene resulting in a susceptibility to a disease or condition associated with abnormal IPMC activity, said kit comprising at least one oligonucleotide primer capable of differentiating between a normal IPMC gene and an IPMC gene with one or more nucleotide differences. Neither SEQ ID Nos 1, 3 or 5 are identified by the specification as such sequences.

Thus, the skilled artisan would be forced into further experimentation to determine those sequences which define a normal IPMC gene, an abnormal IPMC gene, and to determine hybridizing sequences capable of distinguishing the normal IPMC gene from the abnormal IPMC gene. The artisan would further be required to establish those mutations which result in susceptibility to disease. In this regard, the the skilled artisan recognizes the unpredictability in

the art associated with the prediction of peptide function based upon divergent structure, see in particular Skolnick et al., Trends in Biotech 18(1):34-39, 2000, abstract and Box 2 and thus, for those divergent sequences, the skilled artisan would be required to perform further undue experimentation to discover those mutations which possess the properties which result in susceptibility to disease. In addition, the skilled artisan recognizes that nucleic acid hybridization is an unpredictable event which is dependent upon the length of the hybridizing nucleic acids, the sequence homology, the G+C content, temperature and salt concentrations, see in particular Sambrook et al., Cold Spring Harbor Labs, 1989. Yet the specification fails to teach those conditions of hybridization required to define sequences capable of distinguishing normal from abnormal mutations. Thus, for these reasons the skilled artisan would require further undue experimentation to make and to use the recited polynucleotides, hybridizing sequences and kit as claimed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of and "IPMC gene" are indefinite because the skilled artisan lacks direction as to those nucleic acids which are encompassed by the claims.

10. Claim 15 recites the limitation "said ocular disease" in reference to claim 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg et al., Genbank Accession No AA815118, March-5-1998.

AA815118 teaches nucleotide sequence with 100% similarity to residues 3213-3426 of SEQ ID NO:5 and thus hybridizes, see attached alignment.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., Br. Res. Mol. Br. Res., 41(1-2):269-78, 1996.

Wang et al., teach nucleic acids with 100% similarity to SEQ ID NO:5 residues 3222-3259 of SEQ ID NO:6 and thus hybridizes, see attached alignment.

14. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al., Genbank Accession No H38604, August-16-1995.

Hillier et al., teach nucleic acids with 99% similarity to nucleic acids 1262-1640 of SEQ ID NO:3 and to nucleic acids 1262-1573 of SEQ ID NO:5, and thus hybridizes, see attached alignment.

14. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Felbor et al., Genbank Accession No. AF017772, October-28-98 and Cytogenet. Cell Genet., 81:12-17, August-7-1998.

Felbor et al., teach nucleic acids with 99.6% similarity to nucleic acids 1416-1954 of SEQ ID NO:3 and thus hybridizes, see attached alignment.

15. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Strausberg et al., Genbank Accession No. AA721009, January-22-1998.

AA721009 teaches nucleic acids with 100% similarity to nucleic acids 3223-3426 of SEQ ID NO:5 and thus hybridizes, see attached alignment.

Status of Claims

16. No claims are allowed.

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
October, 23, 2000

CHRISTINE SAOUD
PATENT EXAMINER
Christine Saoud